DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 24, 2015

Stryker Trauma Ag
Dr. Heike Gustke
Regulatory Affairs Specialist, Trauma & Extremities
Prof.- Kuntscher- Str. 1-5
Schoenkirchen, 2432 DE
Germany

Re: K151178
Trade/Device Name: Variax 2 Wrist Fusion System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: April 29, 2015
Received: May 4, 2015

Dear Dr. Heike Gustke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151178

Device Name

VariAx 2 Wrist Fusion System

Indications for Use *(Describe)*

The Stryker VariAx 2 Wrist Fusion System is indicated for wrist arthrodesis and fixation of fractures in patients with wrist arthritis or fractures of other small bones of the carpus.
Specific indications include:
- Post-traumatic arthritis of the joints of the wrist
- Rheumatoid wrist deformities requiring restoration
- Complex carpal instability
- Post-septic arthritis of the wrist
- Severe unremitting wrist pain related to motion
- Brachial plexus nerve palsies
- Tumor resection
- Spastic deformities

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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6 510(k) Summary

Proprietary Name:	VariAx 2 Wrist Fusion System
Common Name:	Bone Plates
Regulation Description:	Single/multiple component metallic bone fixation appliances and accessories
Regulation Number:	21 CFR 888.3030
Product Code:	HRS (Plate, Fixation, Bone)
Device Class:	Class II
Sponsor:	Stryker Trauma AG Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Dr. Heike Gustke Regulatory Affairs Specialist Prof.-Kuentscher-Str. 1-5 24232 Schoenkirchen / Germany heike.gustke@stryker.com Phone: +49 4348 702 637 Fax: +49 4348 702 8637
Date Prepared:	April 29, 2015

Description

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the new VariAx 2 Wrist Fusion System.

VariAx 2 Wrist Fusion System is a fixation device that consists of plates with different design (standard bend, short bend, and straight) manufactured from Commercially Pure Titanium Grade 2 (ASTM F67). The plates will be available sterile and non-sterile. VariAx 2 Wrist Fusion System will be used with locking and non-locking screws (2.3mm, 2.4mm, 2.7 and 3.5mm) previously cleared in K040022 (Stryker® Leibinger Universal Distal Radius System), K073527

(VariAx™ Elbow System), K080667 (VariAx™ Distal Radius Torx Screws), and K140769 (VariAx 2 System). VariAx 2 Wrist Fusion System will be used with new and existing instruments previously cleared in K101056 (VariAx Elbow System), K130009 (VariAx 2 Compression Plating System), and K140769 (VariAx 2 System).

Intended Use

The Stryker VariAx 2 Wrist Fusion System is indicated for wrist arthrodesis and fixation of fractures in patients with wrist arthritis of fractures of other small bones of the carpus.

Indications for Use

The Stryker VariAx 2 Wrist Fusion System is indicated for wrist arthrodesis and fixation of fractures in patients with wrist arthritis or fractures of other small bones of the carpus.

Specific indications include:

- Post-traumatic arthritis of the joints of the wrist
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- Complex carpal instability
- Post-septic arthritis of the wrist
- Severe unremitting wrist pain related to motion
- Brachial plexus nerve palsies
- Tumor resection
- Spastic deformities

Summary of Technologies

Device comparison demonstrated that VariAx 2 Wrist Fusion System is substantially equivalent to the Synthes Wrist Fusion Plates (K000558) in regards to intended use, material, design, and operational principles.

Non-Clinical Test

Non-clinical laboratory testing was performed on the worst case subject plates to determine substantial equivalence. Mechanical testing was performed with compliance to ASTM F382-14 ‘Standard specification and test method for metallic bone plates’. Testing demonstrated that

VariAx 2 Wrist Fusion System is equivalent in mechanical performance to the predicate device, the Synthes Wrist Fusion Plates (K000558).

The following testing was performed:

- Dynamic Cantilever Bending Testing (fatigue strength)

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The VariAx 2 Wrist Fusion System is substantially equivalent to the predicate device identified in this premarket notification.